REMARKS

This response addresses the Final Office Action dated, October 29, 2007.

I. Claim Status

Claims 1-17 and 25 are currently pending in the present application and stand rejected. Applicant requests that the Examiner enter presently amended claims 1, and 25. Applicant believes that the claims are now in condition for allowance, and notification to that effect is respectfully requested. The following amendments contain no new matter. This listing replaces all prior versions, and listings of claims in the application.

II. Claim Rejections

1. 35 U.S.C. § 112, First Paragraph

The Examiner has maintained the rejection of claims 1-17 and 25 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner states that one of skill in the art would not recognize from the disclosure that applicant was in possession of the genus which comprises the genus of derivatives of the carrier and the linker.

The Examiner incorrectly states that only a single embodiment is disclosed; "i.e., wherein the peptide is Tyr-Gly-Gly-Phe-Met, carrier is a cinnamoyl, and wherein the linker is -C6 or C8 acidic moiety." See pages 5 of October 29, 2007 Final Office Action. The specification discloses that the peptide can be any therapeutic peptide having less than or equal to 40 amino acid residues. *See* paragraph [0011]. The Specification also discloses that the carrier moiety can be any either of a particular chemical species or derivatives thereof. *See* paragraph [0013].

Moreover, the specification discloses that the linker may also be selected from a discrete set of chemical species that includes C6 to C16 lipidic chains, a 8-amino-3,6-dioxaoctanoic acid and polymers thereof, a natural peptide, a pseudopeptide of less than 4 residues for example, Gly-carba-Gly ([0044]), a peptide mimic of less than 4 residues, palmitoyl ([0044]), aminooctanoyl ([0044]), hydroxyvaleryl-aminoactanoyl ([0044]), and combinations thereof. *See*

paragraph [006], [0015]), and C6-C16 lipids, [0011], [0017]-[0018], [0044], and Example 2. As such, the specification adequately describes the entire genus such that a person of skill in the art would appreciate that the Applicants were in possession of the entire scope of the claims at the time of filing the instant application.

The specification is written for a person of ordinary skill in the art at the time of the invention and, as such, can and preferably does omit that which is known in the art. Union Oil Co. of Cal. v. Atlantic Richfield Co., 208 F.3d 989, 997 (Fed. Cir. 2000). As discussed above, a person of ordinary skill in the art would be able to appreciate what is encompassed by the claims, and would understand that the inventors were in possession of the entire scope of the claim at the time of filing. *See* Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80 (Fed. Cir. 1986) (adequate description requirement is met if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification). Also, it is axiomatic that an Applicant need not provide and example of every embodiment within the scope of the claims in order to satisfy the written description requirement (i.e., an inventor may submit prophetic examples). Union Oil Co., at 997 (a claim's scope does not run afoul of section 112 simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language.). Even in an unpredictable art, patent applicants are not required to disclose every species encompassed by their claims. In re Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991); In re Wallach, 378 F.3d 1330, 1334 (Fed. Cir. 2004).

The Applicant concedes that the skill in the art is very high. However, at the time of the instant invention, pseudopeptides, and peptide mimics were well known and in wide use by those of skill in the art. Therefore, it is unnecessary to expound, ad nauseam, on this topic in the specification. As presented earlier, a person of skill in the art would be well aware of what is meant by "derivatives" of the moieties recited in the claims. Notwithstanding the above, and in order to expedite the allowance of the instant claims, the Applicant has amended claim 1 by deleting reference to "derivatives." As amended, the entire scope of the claims is sufficiently described under 35 USC 112, first paragraph.

Moreover, the instant claims are fully enabled by the specification as filed. Enablement does not mean that "the specification itself must necessarily describe how to make and use every

possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments...." AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003). The Federal Circuit has held that even in an unpredictable art, patent applicants are not required to disclose every species encompassed by their claims. In re Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991); In re Wallach, 378 F.3d 1330, 1334 (Fed. Cir. 2004). Simply because additional experimentation may be necessary does not mean that the specification fails to be sufficient under 35 USC 112, first paragraph. For example, in Wands, the seminal case on enablement, the court held that some, even extensive, research was okay if it would be considered routine by those of skill in the art. 58 F.2d 731, 737 (Fed. Cir. 1988); See also In re Brana, 51 F.2d 1560, 1566 (Fed. Cir. 1993) ("[u]sefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development."); and Ex parte Kubin, Apeal 2007-0819 (BPAI May 31, 2007) ("the amount of experimentation to practice the full scope of the claimed invention might have been extensive, but it would have been routine. The techniques necessary to do so were well known to those skilled in the art.").

As presented previously, the present invention relates to the biopharmaceutical arts. Unquestionably the level of skill in the art is very high. As such, the person of skill in the art could easily make and use the entire scope of the instant invention based upon the description and examples in the specification as filed. In addition, this field of art carries with it the expectation of additional experimentation and testing. However, as the Federal Circuit has recognized, the amount of experimentation, even if extensive, would be considered merely routine, not undue. Accordingly, the instant specification, as filed, is also sufficient to enable the present invention in accordance with 35 USC 112, first paragraph.

Therefore, Applicant maintains that the specification provides adequate disclosure to allow persons of ordinary skill in the art to recognize that Applicants were in possession of the entire scope of what is claimed. Notwithstanding the above, the Applicant has amended the claims for simplicity and clarity. As such, the Applicant respectfully requests that the Examiner withdraw this grounds for rejection.

Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

CONCLUSION

Applicant honestly believes that all aspects of the present Office Action have been sufficiently addressed and submits that the present application is now in condition for allowance, and notice to that effect is respectfully requested.

If the Examiner believes that a telephone conference with Applicants' attorneys would be advantageous to the disposition of this case, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Applicant believes that fees for a one-month extension of time are due in association with entry of the current response. As such, the Commissioner is hereby authorized to charge Deposit Account No. 50-3569 in the amount of $60.00 for a one-month extension of time for a Small Entity. However, if any fee has been inadvertently overlooked and is required, Commissioner is hereby authorized to debit any fee due or credit any overpayment to Deposit Account No. 50-3569.

Respectfully submitted,

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